

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Rec'd PCT/PTO 12 OCT 2004

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Applicant's or agent's file reference LABAP29480PC	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IT 02/00231	International filing date (day/month/year) 12.04.2002	Priority date (day/month/year) 12.04.2002
International Patent Classification (IPC) or both national classification and IPC A61K39/295		
Applicant CAPUA, Ilaria		


1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- | | | |
|------|-------------------------------------|--|
| I | <input checked="" type="checkbox"/> | Basis of the opinion |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input type="checkbox"/> | Certain observations on the international application |

Date of submission of the demand 11.11.2003	Date of completion of this report 28.07.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Turri, M Telephone No. +49 89 2399-7712



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/IT 02/00231**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

Description, Pages

1-41 as originally filed

Claims, Numbers

1-14 received on 24.06.2004 with letter of 23.06.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-9, 12-14
	No: Claims	10, 11
Inventive step (IS)	Yes: Claims	1-9, 12-14
	No: Claims	10, 11
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following document:

D4: CAPUA LDARIA ET AL: "Strategies for the control of avian influenza in Italy." THE VETERINARY RECORD. ENGLAND 16 FEB 2002, vol. 150, no. 7, 16 February 2002 (2002-02-16), page 223, XP009004791 ISSN: 0042-4900

D8: SWAYNE D E ET AL: "Highly pathogenic avian influenza." REVUE SCIENTIFIQUE ET TECHNIQUE OFFICE INTERNATIONAL DES EPIZOOTIES, vol. 19, no. 2, August 2000 (2000-08), pages 463-482, XP001122269 ISSN: 0253-1933

2. Document D4 discloses a "DIVA" strategy for differentiating vaccinated animals from infected based on the use of an inactivated vaccine containing the same haemoagglutinin (H) subtype as the field virus, but a different neuraminidase (N). In particular, an inactivated vaccine containing an H7N3 strain was used to vaccinate H7N1 infected animals. After the first year of vaccination, the epidemiological data collected indicated that the H7N1 virus was not circulating any longer, demonstrating the efficacy of the vaccination scheme.
3. Present claim 10 is directed to a process for vaccinating animals against avian influenza virus, comprising the preparation of an "heterologous" vaccine characterized by the same subtype of viral haemagglutinin and a different subtype of neuraminidase.
4. Said method comprises, as last step, the use of the method of the preceding claims 1-9 to determine whether the animal is infected with the virus. However, a process for vaccinating an animal against a virus is certainly independent from the method that is used to determine if the animal is infected with the virus. In other words, the method of claims 1-9 is not an essential feature of the process for vaccinating of claim 10, because other diagnostic methods known in the prior art can be used to test the results.
5. Therefore, the subject-matter of claims 10 and 11 is not new in the sense of Article 33(2) PCT.

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6. Document D1, which is considered to represent the most relevant state of the art with regard to the subject-matter of claims 1 and 12, discloses diagnostic tests for avian influenza virus, AGID and ELISA, both based on the detection of antibodies against nucleoprotein (page 471, first and second full paragraphs), from which claims 1 and 12 differs in that the diagnostic test is based on the detection of anti-neuraminidase antibodies.
7. The problem to be solved by the present invention may be regarded as the provision of an alternative diagnostic test for avian influenza virus. The solution to this problem proposed in the present application is considered as involving an inventive step (Article 33(3) PCT), since there are no suggestions in the prior art that the neuraminidase could be used to detect the infection with avian influenza virus.
8. Dependent claims 2-9, 13 and 14 also meet the requirements of the PCT with respect to novelty and inventive step.